Remarks

In the Office Action mailed October 5, 2007, the examiner has required restriction of the application to one of two inventions, the Invention of Group I, Claims 1-76, or the Invention of Group II, Claims 77-128. Group I is drawn to a system comprising a therapeutic protein formulation and an implantable catheter system. Group II is drawn to a therapy or method of delivering a therapeutic protein formulation.

The examiner states that the inventions of Group I and Group II are related as product and process of use. However, in the instant case, the product of Group I can be used in the materially different process of delivering therapeutic protein formulations to another area in a patients body where catheters are generally utilized such as in various organs or blood vessels or alternatively in organ transplants treated ex vivo before any transplant operation.

Furthermore, the examiner has required a first and second specie election. The first specie relates to species of neurological diseases and the related appropriate or enzyme. The second specie relates to a specific type of chemical structure/formulation for the modified therapeutic protein and includes Specie A) is the absence of a protein modification as a transport aid to provide for enhanced cellular uptake or Specie B) wherein there is a presence of a protein modification as a transport aid to provide for enhanced cellular uptake.

The examiner maintains that the neurological diseases and related enzyme of the first species are independent or distinct because each combination of disease/therapeutic protein formulation results in treatment of distinct diseases, each of which are well known to exist in a patient via distinct modes of action, which is further substantiated by said diseases being separately named and studied as to their course and treatment thereof.

Similarly, the examiner maintains that the second species are independent or distinct because each specie (absence or presence of modified protein) of the therapeutic protein formulation presents distinct issues regarding delivery and efficacy, especially the presence of a transport aid for which each specifically interacts with cellular membranes and cell surface chemistry to affect transport or not, depending on which specie is elected.

In light of the foregoing, Applicant hereby elects GROUP I, Claims 1 through 76, without traverse, for continued prosecution. As to the election of a first species, however, Applicant elects GM2-gangliosidosis Type 1, also known as Tay-Sachs disease as the neurological disease and beta-hexosamindase A as the related enzyme, with traverse as to the first specie restriction. As to the second specie restriction, Applicant elects Specie A), the absence of a protein modification as a transport aid to provide for enhanced cellular uptake, with traverse to the second specie restriction. Both specie are encompassed by the elected claims 1-76 of Group I.

Applicant traverses the species restrictions only, because, while the diseases and related proteins/enzymes involved are distinct, each is involved neurologically in a lysosomal storage disease and as such does not impose an undue burden of search and examination on the examiner. Furthermore, whether there is a protein modification or not does not impose an undue burden of search and examination. The operation and effect of the claimed specie are related.

Moreover, the examiner has not shown a prima facie "serious burden" of search and/or examination. The examiner has not shown or provided evidence that the diseases, proteins or enzymes involved or absence of protein modification are each contained within separate classifications, status in the art, or as being in a different field of search. MPEP 808.02. Indeed,

the examiner has not presented any information regarding classification thereof where any species has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Prior art uncovered for one species may be applicable to another because of the related function.

In closing, based on the foregoing, Applicant does not traverse the restriction requirement based on the invention/claim grouping. Applicant traverses the first and second specie restriction only. The election of the species, therefore, is made with traverse and Applicant reserves its right to petition the requirement of an election of first and/or second species and on this basis only.

The present paper constitutes a complete response to the Office Communication mailed October 5, 2007. Applicant respectfully requests reconsideration of the application in light of the remarks. Applicant requests that this case be allowed and pass to issuance.

Respectfully submitted,

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